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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

DAMIAN FRANTZ, a single man, Plaintiff vs. SUN PHARMACEUTICALS, a foreign corporation, Defendant.	Case No.: **COMPLAINT**

For his Complaint against Sun Pharmaceuticals ("Defendant," "the Company," or "Sun"), Plaintiff Damian Frantz ("Plaintiff" or "Mr. Frantz"), referred to jointly as "the parties," allege as follows:

Background Allegations and Jurisdiction

1. Plaintiff reasonably believes that Defendant violated various provisions of the False Claims Act ("FCA") as outlined below. *See* 31 U.S.C. § 3729, *et seq.*

2. Though, upon information and belief, Plaintiff alleges that Defendant's scheme caused false claims to be submitted to the Government and further believes that the Government paid those false claims, Plaintiff does not have sufficient detail to support that allegation at this time. However, in raising those concerns to Defendant, Plaintiff was disciplined and retaliated against.

3. As such, Plaintiff brings this claim for Defendant's retaliation and discharge of him after reporting these unlawful activities in violation of 31 U.S.C. § 3730(h).

4. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331,1345, and 31 U.S.C. § 3730(h).

5. Venue is appropriate because Defendant transacts business in this judicial district. Additionally, Defendant has committed acts proscribed by 31 U.S.C. § 3730(h) in this judicial district.

6. Plaintiff is a citizen of the United States of America and resides in the State of Arizona.

7. At all relevant times in this Complaint, Plaintiff was a pharmaceutical sales associate for Defendant.

8. Upon information and belief, none of the alleged violations of the FCA have been publicly disclosed, until this filing, in any manner and Plaintiff is the original source of the information upon which this Complaint is based, as that term is used in the FCA.

9. Defendant Sun Pharmaceuticals is a foreign corporation doing business in the State of Arizona, and transacting business in every state of the United States.

10. As part of his employment, Defendant directed Plaintiff to facilitate and solicit "off-label" marketing for certain drugs.

11. Defendant acted through its agents and employees, and the actions of those agents and employees were within the course and scope of their employment.

12. Defendant's off-label marketing campaign was (and continues to be), upon information and belief, approved at the highest levels.

Regulatory Landscape and Governing Law

13. The Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §1395 *et seq.*, (hereinafter "Medicare") is a Health Insurance Program administered by the Government of the United States that is funded by taxpayer revenue. The program is overseen by the United States Department of Health and Human Services through the Centers for Medicare and Medicaid Services ("CMS"). Medicare was designed to be a health insurance program and to provide for the payment of hospital services, medical services and durable medical equipment to persons over sixty-five (65) years of age and

others that qualify under the terms and conditions of the Medicare Program. Payments made under the Medicare Program include payment for certain prescription drugs; among those at issue in this case, Ilumya, Yonsa, and Absorica.

14. Reimbursement for Medicare claims is made by the United States through CMS which contracts with private insurance carriers to administer and pay claims from the Medicare Trust Fund. 42 U.S.C. § 1395u. In this capacity, the carriers act on behalf of CMS.

15. The Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v (hereafter "Medicaid"), is a Health Insurance Program administered by the United States and the various individual States, and is funded by State and Federal taxpayer revenue. The Medicaid Program is overseen by the United States Department of Health and Human Services through CMS. The States directly pay providers, with the States obtaining the federal share of the payment from accounts which draw on the United States Treasury. 42 C.F.R. §§ 430.0-430.30 (1994). Medicaid was designed to assist participating states in providing medical services, durable medical equipment and prescription drugs to financially needy individuals that qualify for Medicaid; among those drugs are the drugs at issue in this case, Ilumya, Yonsa, and Absorica.

16. The Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS") (now known as "TRICARE"), 10 U.S.C. §§ 1071-1106, provides benefits for health care services furnished by civilian providers, physicians, and suppliers to members of the Uniformed Services and to spouses and children of active duty, retired and deceased members. The program is administered by the Department of Defense and funded by the Federal Government. CHAMPUS pays for, among other items and services, prescription drugs for its beneficiaries; among those drugs are the drugs at issue in this case, Ilumya, Yonsa, and Absorica.

17. The federal government, through its Departments of Defense and Veterans Affairs, also maintains and operates medical facilities including hospitals, and receives and uses federal funds from prescription drugs for patients treated at such facilities and

otherwise; among those drugs are the drugs at issue in this case, Ilumya, Yonsa, and Absorica. In addition, under the Public Health Service Act, the Section 340B Drug Pricing Program, and the Veterans Health Care Act of 1992, the federal government directly or indirectly provides funds to certain other federal agencies and to state and local facilities and programs, including to non-profit disproportionate share hospitals ("DSH") and Federally Qualified Health Centers ("FQHCs"). *See* 38 U.S.C. § 8126.

18. The Federal Employees Health Benefits Program ("FEHBP") provides health care benefits for qualified federal employees and their dependents. It pays for, among other items and services, prescription drugs for its beneficiaries; among those drugs are the drugs at issue in this case, Ilumya, Yonsa, and Absorica.

19. The Federal FCA, 31 U.S.C. § 3729(a)(1)(A), makes "knowingly" presenting or causing to be presented to the United States any false or fraudulent claim for payment or approval a violation of federal law for which the United States may recover three times the amount of the damages the government sustains and a civil monetary penalty of between $5,500 and $11,000 per claim.

20. The Federal FCA, 31 U.S.C. § 3729(a)(1)(B), makes "knowingly" making, using, or causing to be used or made a false record or statement material to a false or fraudulent claim paid or approved by the Government a violation of federal law for which the United States may recover three times the amount of the damages the Government sustains and a civil monetary penalty of $5,500 and $11,000 per claim.

21. The Federal FCA, 31 U.S.C. §. 3729(a)(1)(C), makes any person who conspires to commit a violation of the FCA liable for three times the amount of the damages the Government sustains and a civil monetary penalty of between $5,500 and $11,000 per claim.

22. The Federal FCA, 31 U.S.C. § 3729(a)(1)(G), makes any person who "knowingly" makes, uses or causes to be made or used a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit

money or property to the Government, liable for three times the amount of the damages the Government sustains and a civil monetary penalty of $5,500 and $11,000 per claim.

23. The Federal FCA defines a "claim" to include any request or demand, whether under contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested. *See* 31 U.S.C. § 3729(b)(2).

24. Physicians and hospitals enter into Provider Agreements with CMS in order to establish their eligibility to seek reimbursement from the Medicare Program. As part of that agreement, without which the hospitals and physicians may not seek reimbursement from Federal Health Care Programs, the provider must sign the following certification:

> "I agree to abide by the Medicare laws, regulations and program instructions that apply to [me]. The Medicare laws, regulations, and program instructions are available through the [Medicare] contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the [provider's] compliance with all applicable conditions of participation in Medicare."

See Form CMS-855A; Form CMS-8551.

25. In addition, the claims themselves, as submitted, contain a similar certification. *See, e.g.*, Form CMS-1500.

26. When a provider submits a claim for payment, he or she does so subject to and under the terms of its certification to the United States that the services for which payment is sought were delivered in accordance with federal law.

27. In the case of Medicaid, each State's Medicaid Program's applicable certifications also incorporate relevant state law.

28. To be properly reimbursable by a Government Health Care Program, a prescription drug must also meet certain other requirements involving whether the drug is prescribed for an "on-label" versus an "off-label" use or indication.

29. The Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. §§ 301, *et seq*., prohibits the distribution of new pharmaceutical drugs in interstate commerce unless the Food and Drug Administration ("FDA") has determined that the drug is safe and effective for its intended use. 21 U.S.C. § 355 (a) and (d).

30. An approved drug may be prescribed by doctors for uses other than those approved by the FDA, but manufacturers are prohibited from marketing or promoting the drug for such unapproved or "off-label" uses. *See* 21 U.S.C. § 331(d). If the manufacturer intends to promote the drug for a new unapproved use, an application for the proposed new use must be filed with the FDA (or an exemption therefrom must be obtained) and any promotional materials concerning unapproved uses must meet strict statutory and regulatory requirements. *See* 21 U.S.C. §§ 360aaa, *et seq.*

31. Whether a drug is FDA-approved for a particular use determines whether a prescription of the drug is reimbursed under Government Health Insurance Programs, including those described above.

32. Reimbursement under Medicaid and these other programs is generally available only for "covered outpatient drugs." *See* 42 U.S.C. §1396b(i)(10). Covered outpatient drugs do not include drugs that are "used for a medical indication which is not a medically accepted indication." *Id*. §1396r-8(k)(3). A medically accepted indication includes a use "which is approved under the Federal Food Drug and Cosmetic Act" or which is included in a specified drug compendia. *Id.* §1396r-8(k)(6).

33. Unless a particular off-label use for a drug is included in one of the identified drug compendia, a prescription for the off-label use of that drug is not eligible for reimbursement under Medicaid, with a limited exception. *See* 42 U.S.C. §1396r8(a)(3).

34. The FFDCA provides criminal penalties for the dissemination of written information to health care providers regarding the safety, effectiveness, or benefit of the use

of a drug that is not described in the FDA approved labeling of the drug (i.e. that is "off-label"), if that written information fails to conform to the law's requirements. *See* 21 U.S.C. §§ 331(z), 333(a)(1)-(2), 360aaa. A manufacturer may disseminate information on a new use of a drug only if it meets the specific requirements set forth in 21 U.S.C. § 360aaa.

35. As outlined below, several states have passed False Claims Act legislation, which closely tracks the Federal FCA: California False Claims Act, Cal. Gov't Code § 12650 *et seq.*, Delaware False Claims and Reporting Act, Del. Code Ann. Tit. 6, § 1201 *et seq.*, District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.13 *et seq.*, Florida False Claims Act, Fla. Stat. § 68.081 *et seq.*, Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq.*, Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/1 *et seq.*, Louisiana Medical Assistance Programs Integrity Law, 46 La. Rev. Stat. c. 3, sec. 437.1 *et seq.*, Massachusetts False Claims Act, Mass. Gen. Laws Ch. 12, § 5A *et seq.*, Nevada False Claims Act, Nev. Rev. Stat. § 357.040 *et seq.*, Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*, Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Chapter 32, § 36.002 *et seq.*, Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq.* , Va. Code Anno. 49-4-168 *et seq.*; Indiana, IC 5-11-5.5; Michigan Medicare False Claims Act, MI ST Ch. 400, 400.602 *et seq.*; New Hampshire False Claims Act, N.H. RSA §§ 167:61-b *et seq.*; New Jersey False Claims Act, Sec. 2A:32C-1 *et seq.*; New Mexico Fraud Against Taxpayers Act, N.M. LEGIS 49 (2004 AND 2007) Chap. 4; New York State False Claims Act, 2007 New York Laws 58, Sec. 39, Article XIII, Sec. 189(a) *et seq.*; Oklahoma Medicaid False Claims Act, 2007 OK. ALS 137; Rhode Island False Claims Act, Sec. 9-1.1-1 *et seq.*; Wisconsin False Claims for Medical Assistance Act, Chapter 20, Subchapter 91, 20.931. These State False Claims Acts apply to the state portion of Medicaid fraud losses caused by false Medicaid claims to the jointly federal-state funded Medicaid program. Each of the statutes listed above contains *qui tam* provisions governing a relator's right to claim a share of the State's recovery.

36. Furthermore, the Federal FCA, 31 U.S.C. § 3730(h), provides relief to employees who have been retaliated against in their employment because of lawful acts done by the employee in furtherance of efforts to stop one or more violations of the FCA. Such retaliation may include discharge, demotion, suspension, threats, harassment or any other type of discrimination in the terms and conditions of employment. The employee is entitled to all relief necessary to make that employee whole, including reinstatement, two times back pay, interest on the back pay, and compensation for any special damages, including litigation costs and reasonable attorney's fees.

37. Plaintiff reasonably believes that Defendant violated the Federal and State FCAs and the FFDCA by engaging in the following alleged conduct from at least 2016 to the present, involving the marketing, selling, and prescribing of Ilumya, Yonsa, and Absorica, which drugs Defendant knew was paid for, in part, by Federal Health Care Programs, and which drugs Defendant expected health plans, insurance companies, pharmacy benefit management companies, and individual providers, as well as numerous other unnamed persons around the United States to, directly or indirectly, prescribe and administer to their patients and thereafter illegally bill or cause to be billed to Federal Health Care Programs.

38. Plaintiff reasonably believes that Defendant's schemes included, but are not limited to the following actions, all of which violate the Federal and State FCAs:

a. Conspiring to create unlawful incentives to provide in exchange for patient referral and prescription business;

b. Conspiring to make and use false records and statements to get false claims paid by the Government;

c. Conspiring to defraud the Government by getting false or fraudulent claims allowed or paid by the Government in furtherance of the object of the conspiracy, which was to promote and increase the sales;

d. Knowingly making and using a false record or statement to conceal, avoid or decrease obligations to pay or transmit money or property to the Government;

e. Illegal off-label marketing of; and

f. Retaliating against Plaintiff and other unlawful activities as described in this Complaint.

THE FORUMULARY: A PRACTICE THAT OVERRIDES THE POLICY

39. Plaintiff reallege paragraphs 1-38 as if fully set forth here.

40. In and around 2016, Defendant developed and distributed policies that purported to prohibited unlawful conduct.

41. In particular, Defendant's "policies" prohibited sales associates from discussing off-label uses for their drugs. Rather, Defendant's "policy" required a written solicitation from a third party in order any off-label information. Upon receiving the written solicitation, Defendant's clinical team would meet with the requestor to provide any clinical information beyond that on label, as indicated.

42. Requestors could be health plans, insurance companies, physicians, pharmacy benefit management companies, and others with decision-making authority to prescribe, recommend, promote and/or add to a company's formulary the Defendant's drugs.

43. In addition, Defendant's "policy" required written material provided to third parties be approved and unmodified by its clinical team. According to Defendant, this "policy" was designed to prevent unlawful marketing and promotion of its drugs. The "policy" purportedly promoted public safety by not introducing a new drug or use into commerce without Government approval.

44. In and around 2016 to present, Defendant developed and implemented practices that directly contravened its written policies.

DIRECTIONS TO PLAINTIFF: SOLICIT, FACILITATE, AND COVER UP

45. Defendant's practice includes soliciting health plans, insurance companies, physicians, pharmacy benefit management companies, and others with decision-making authority to prescribe, recommend, promote and/or add to a company's formulary the Defendant's drugs.

46. In May 2018, Plaintiff was expressly directed to solicit and facilitate presentations for health plans, clients, potential clients, and any decision-maker that could purchase or promote Defendant's drugs.

47. Particularly, Plaintiff's supervisor, Defendant's Associate Vice President of Sales, Janet Sharp, told him to "do whatever is needed to get" the clinical team in there to "talk off label" and "sell."

48. In August 2018, Ms. Sharp again directed Plaintiff to solicit clinical team presentations to "talk off label" and "sell" or he would lose his job.

49. Defendant's practice was not to require any unsolicited request. In fact, Defendant's practice was to aggressively solicit opportunities to present off-label information to decision-makers about its drugs.

50. To avoid detection, Defendant, via Ms. Sharp and others, instructed its sales members not to put such solicitations in writing, but to make the pitch in person, over the phone, or in any untraceable manner.

51. In fact, Defendant would sometimes "drag" someone from its clinical team to a client meeting to present off-label material in the absence of any request. In one example, in October 2018, Defendant instructed Plaintiff to take a clinical team member to Kaiser to engage in off-label discussions and unlawful promotion. Kaiser had not requested nor desired any clinical presentation.

52. After sales members successfully solicited a decision-maker, Defendant instructed its employees to "create" a document that made it appear as though the request was unsolicited.

53. Following suit, Defendant provided instructions about this unlawful off-label and unsolicited marketing during teleconferences and in one-on-one meetings.

54. Further, Defendant's practice was not to exclusively utilize pre-approved marketing material. Rather, Plaintiff witnessed selective inclusion and exclusion of certain material within the pre-approved slide decks. The purpose of such inclusion and exclusion

was expressly to persuade the decision-maker/health plan administrator to prescribe, promote, or give certain formulary status to Defendant's drugs.

55. Defendant's bonus system compensated its sales members, in part, for success in soliciting and facilitating unsolicited clinical presentations.

56. The converse was also true.

RETALIATION AND MALICIOUS INTENT

57. Plaintiff raised concerns about the Defendant's practices on multiple occasions. Specifically, Plaintiff noted that the Defendant's policy complied with the law but the practice violated several. Plaintiff objected to Defendant's solicitation and off-label marketing practices and told Defendant that they believed the practices violated the FCA and Anti-Kickback Statute.

58. Plaintiff relayed the concern that presenting unapproved promotional material violated the FCA and Anti-Kickback Statute.

59. Prior to engaging in this protected activity, Plaintiff was recognized as Defendant's National Account Manager of the Year in 2016.

60. As a direct result of the protected activity, Plaintiff was deprived of compensation.

61. Plaintiff had historically earned bonuses at 100%; immediately after raising his concerns with Defendant, Plaintiff's bonuses were significantly depleted because: (1) he raised his concerns about the unlawful conduct; and (2) he refused to participate in soliciting off-label discussions as Plaintiff believed it violated federal law.

62. Immediately after raising these concerns, Plaintiff was placed on a Performance Improvement Plan ("PIP").

63. In his PIP, Defendant required Plaintiff to solicit clinical presentations and facilitate off-label marketing. Plaintiff believed this required conduct, for which he was subjected to corrective action, was unlawful.

64. Plaintiff again complained to Human Resources and Defendant's Compliance Department that he believed such solicitations and off-label marketing violated FCA, the

Anti-Kickback Statute, and internal Defendant policies. In fact, Plaintiff relayed that, to the extent that his impression was incorrect, he wanted Defendant to inform him about his misunderstanding.

65. Plaintiff had several meetings with Ms. Sharp and Human Resources wherein he was directed to solicit off-label presentations. It continued to be a required part of his PIP.

66. Plaintiff recorded these meetings.

67. Defendant reaffirmed its expectations of Plaintiff that he firmly believed, and reported, violated the law.

68. Plaintiff put these concerns in writing, spoke with the Defendant's Compliance Department, and provided documentation in support.

69. Plaintiff provided statutory notice about his intention to leave if the matter was not remedied.

70. Plaintiff reasonably believed that he could be held liable, civilly and criminally, if he conformed with Defendant's off-label marketing scheme.

71. As such, Plaintiff was constructively discharged from his employment in June 2019.

ADDITIONAL RETALIATORY CONDUCT

72. Even prior to his constructive discharge, Plaintiff's decreased compensation and PIP – all because he refused to violate the FCA and put Defendant on notice – Defendant engaged in additional retaliation.

73. After Plaintiff refused to solicit clinical presentations for targeted health plans, Defendant (via Ms. Sharp) told Plaintiff in a conference call, with others in attendance, to "cover his ears" because she knew the direction about unlawful solicitation would make Plaintiff "uncomfortable."

LEGAL CLAIM
RETALIATION / FALSE CLAIMS ACT

74. Plaintiff realleges each allegation contained in paragraphs 1 through 73 as if fully set forth here.

75. Plaintiff reasonably believed, and still believes, that Defendant's conduct violated the FCA and other federal and state laws.

76. Plaintiff reported the violations on multiple occasions to Defendant's Associate Vice President of Sales, to Defendant's Human Resources Department, and to Defendant's Compliance Department.

77. Plaintiff made these reports, each time, in an effort to stop violations of the FCA and other federal and state laws.

78. As a result of these reports, Defendant was deprived of compensation, disciplined, threatened with his job (in the same conversation as one of these reports), harassed, and constructively discharged.

79. Further, Plaintiff's PIP required him to engage in what he believed (and reported) was unlawful conduct. Plaintiff reasonably believed that he could be held civilly and criminally liable if he engaged in such conduct mandated by Defendant.

80. Plaintiff put these concerns in writing to Defendant.

81. Plaintiff was constructively discharged in June 2019.

82. Defendant's conduct violated the anti-retaliation provision of the FCA. *See* 31 U.S.C. 3730(h)(1).

83. As a result, Plaintiff is entitled to relief as outlined in Section 3730(h)(2), including back pay, double damages, compensatory damages, front pay, special damages, and attorneys' fees and costs.

Conclusion

THEREFORE, Plaintiff respectfully requests the following relief:

A. An award of damages to be proven at trial, in all categories, as specified in Section 3730 of the FCA;

B. An award of liquidated damages in an amount appropriate to the proof adduced at trial;

C. Attorneys' fees and costs; and

D. Pre- and post-judgment interest.

DATED this 10th day of July 2019.

The Foster Group, PLLC

/s/ Troy P. Foster

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